IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC. Defendants.	)	C.A. No. 22-252 (MSG) **REDACTED - PUBLIC VERSION**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	)	

DEFENDANTS' BRIEF IN SUPPORT OF THEIR MOTION TO SEAL PORTIONS OF PLAINTIFFS' AMENDED COMPLAINT (D.I. 301)

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I. INTRODUCTION

Pursuant to the Protective Order (D.I. 91) as modified by the Court's November 14, 2023 Order (D.I. 155), Defendants Moderna, Inc. and ModernaTX, Inc. ("Moderna") respectfully move this Court to seal Moderna's sensitive and confidential information and to grant leave to file a partially redacted version of Plaintiffs' Amended Complaint for Patent Infringement (D.I. 301) ("Amended Complaint"). As explained in more detail below, the portions marked for redaction contain Moderna's sensitive and confidential technical information, including confidential trade secrets.

In support of this motion, Moderna attaches as Exhibit A the Declaration of Don Parsons, Vice President of Delivery Science and Development at ModernaTX, Inc., who is knowledgeable about Moderna's confidential information that Moderna seeks to seal and is familiar with its sensitivity. The Amended Complaint contains Moderna's highly confidential information, and the Court should maintain that material under seal in order to prevent serious and real harm to Moderna. Release of Moderna's highly confidential information to the public and Moderna's competitors would create a clearly defined and serious injury to Moderna, as discussed in detail below.

II. LEGAL STANDARD

Third Circuit common law presumes a public right of access to judicial records; however it also protects business and financial information when access would cause economic harm, including competitive harm. *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). "Although the common law right to public access is a recognized and venerated principle, courts have also recognized the accompanying principle that the right is not absolute." *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001) (citations and quotations omitted); *see also Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) ("Despite the

presumption, courts may deny access to judicial records, for example, where they are sources of business information that might harm a litigant's competitive standing.").

This presumption is overcome where a movant shows "that the interest in secrecy outweighs the presumption." *In re Avandia Mktg.*, 924 F.3d at 672 (quoting *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). This showing may be made by demonstrating that disclosure will work a clearly defined and serious injury to the movant and that the material is the kind of information that courts will protect. *See In re Avandia Mktg.*, 924 F.3d at 672 (citing *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)). The Court will apply a "good cause" standard justifying sealing or redacting judicial records, requiring a "balancing process, in which courts weigh the harm of disclosing information against the importance of disclosure to the public." *Mosaid Techs. Inc. v. LSI Corp.*, 878 F. Supp. 2d 503, 507-08 (D. Del. 2012) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 (3d Cir. 1994)).

III. ARGUMENT

Good cause exists here to seal or partially seal paragraphs 56–58, 77–78, 98–99, 119–120, 143–144, 169–170, and 190–191 of the Amended Complaint because these paragraphs contain Moderna's highly confidential technical and business information. Disclosure of such information would cause real and serious competitive harm to Moderna and the information does not need to be disclosed to the public to understand the filings at issue.

Although the public's presumptive common law right of access to judicial records attaches to materials filed in connection with a pretrial motion of a non-discovery nature, this right is "not absolute" and may be overcome by a showing that the material sought to be sealed "is the kind of information that courts will protect and will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg.*, 924 F.3d 662, 673 (3d Cir. 2019)

(citation omitted). Here, the material Moderna seeks to redact from the Amended Complaint is the type of limited information of the kind that courts in the Third Circuit have recognized as protectable, namely highly sensitive and confidential technical information regarding Moderna's proprietary and trade secret manufacturing methods for its COVID-19 Vaccine, including steps in the manufacturing process and parameters for those steps.

The harms caused by revealing Moderna's confidential information are discussed below, and further in the attached declaration of Don Parsons (Exhibit A), Vice President of Delivery Science and Development at ModernaTX, Inc., who is familiar with this information and its sensitivity. As Dr. Parsons explains, there is significant competition between established vaccine suppliers, including suppliers with mRNA-based vaccines, like Moderna, and any information about one of these competitors, even seemingly minor information, may prove competitively advantageous. Ex. A, ¶ 7.

Moderna seeks only to partially seal the Amended Complaint. As described briefly below, and further explained in the Declaration of Don Parsons, the portions Moderna seeks to redact contain Moderna's confidential information, including highly confidential and sensitive information regarding Moderna's proprietary technology relating to its manufacturing methods for its COVID-19 Vaccine, known as mRNA-1273 or "SpikeVax." Ex. A, ¶¶ 6–9. SpikeVax is comprised of messenger RNA (mRNA) which is delivered using lipid nanoparticles (LNPs). *Id.*, ¶ 3. Moderna's proprietary LNP is comprised of four lipid components including SM-102, cholesterol, phospholipid, and a polyethylene glycol (PEG) lipid conjugate. *Id.* With respect to Moderna's formulation, Moderna considers its precise formulation, including the specific quantities of ingredients, a trade secret, which is not public knowledge. *Id.*, ¶ 8. With respect to Moderna's manufacturing process for SpikeVax, Moderna considers its process-as-a-whole a

trade secret, including the steps in the process, the records of each step, the parameters or specification for each step (such as timing, sequence, amount and kind of raw materials, temperatures, measurements, equipment used etc.). *Id.*, ¶ 9. Moderna has not publicly disclosed its proprietary manufacturing process. *Id.*

Specifically, Moderna has not publicly disclosed information within the Amended Complaint. Paragraphs 56–58, 77–78, 98–99, 119–120, 143–144, 169–170, and 190–191 disclose specific information concerning the composition of Moderna's COVID-19 Vaccine and Moderna's proprietary and trade secret manufacturing methods for its COVID-19 Vaccine including steps in the manufacturing process and parameters for those steps.

Because of the highly competitive nature of the vaccine supplier market, Moderna has spent significant effort and resources to develop these manufacturing methods and formulations and the release of such information to the public, including Moderna's competitors, would harm Moderna. Ex. A, ¶ 7. Because there are so few competitors in the vaccine supplier market, the market is highly competitive, and any information about one of the competitors, even seemingly minor information, may prove competitively advantageous. *Id.* Additionally, there are companies considering entering the vaccine market and companies developing mRNA-based vaccines and therapeutics for other diseases or developing lipid nanoparticles for mRNA-based products. *Id.*

If the confidential information were made public, Moderna's competitors would be able to potentially replicate Moderna's products, features within Moderna's products, and methods of making mRNA-LNP products, or make decisions about where, when, and how to offer directly competitive goods with full knowledge of Moderna's technology. Ex. A, ¶ 10. Moderna's competitors would gain a significant advantage in creating their own business

strategies, which would put Moderna at a significant competitive disadvantage, causing it real and serious harm. *Id.* Moderna's competitors may also seek patent claims to cover Moderna's technology. *Id.*

Moderna has always taken extensive measures to maintain the confidentiality of its technical information. Ex. A, ¶ 5. Moderna has been extremely concerned about the protection of its confidential information during this litigation and has been very careful to always protect this information. *Id.* Moderna has invested significant resources to develop this information as well, *id.*, ¶ 7, and this information is of the type that courts have recognized as protectable. *See, e.g.*, *Nitto Denko Corp. v. Hutchinson Tech. Inc.*, No. CV 16-3595 (CCC/MF), 2017 WL 2782639, at *2 (D.N.J. Mar. 3, 2017) (granting motion to seal "confidential technical information" where such information "was not intended to be seen by competitors . . . for review and potential use against the parties" and parties were in "highly competitive [] industry"); *Guardant Health, Inc. v. Foundation Med., Inc.*, C.A. Nos. 17-1616-LPS-CJB, D.I. 447 (D. Del. Jun. 16, 2020) (granting motion to redact confidential information concerning defendant's confidential technical information).

Disclosure of Moderna's confidential information regarding either the technical details of Moderna's precise formulation and the proprietary manufacturing process for SpikeVax would "work a clearly defined and serious injury" to Moderna, as such disclosure would provide Moderna's competitors, customers, and potential licensors or licensees with otherwise confidential information regarding Moderna's products and strategies, as well as a competitive advantage in both the vaccine supplier market and in negotiations with Moderna. *See Pansy*, 23 F.3d at 786. Moreover, because this "case involves private litigants" and their confidential information, there is "little legitimate public interest" in the proposed redactions. *Id.* at 788.

Under such circumstances, Moderna's interest in maintaining the confidentiality of the proposed redacted information outweighs any countervailing public interest. *See id.* ("[I]f a case involves private litigants, and concerns matters of little legitimate public interest, that should be a factor weighing in favor of granting or maintaining an order of confidentiality."); *Leucadia, Inc. v. Applied Extrusion Tech., Inc.*, 998 F.2d 157, 166 (3d Cir. 1993) ("Documents containing trade secrets or other confidential business information may be protected from disclosure" and explaining that the court has "framed the inquiry as whether the need for secrecy outweighs the presumption of access that normally attaches to such documents"); *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978) ("[C]ourts have refused to permit their files to serve as … sources of business information that might harm a litigant's competitive standing.").

As explained above, paragraphs 56–58, 77–78, 98–99, 119–120, 143–144, 169–170, and 190–191 of the Amended Complaint contain technical details regarding Moderna's proprietary LNP formulation in SpikeVax and the related proprietary manufacturing process. Moderna's proposed redactions to the Amended Complaint redact the specific confidential material at issue, leaving the remainder unredacted. These proposed redactions are narrow such that the public's ability to understand the Amended Complaint is not impaired any less than necessary to prevent the release of Moderna's most sensitive technical information to its competitors, preventing clear competitive harm. Moderna's proposed redactions are narrow in scope and refer only to Moderna's confidential, sensitive technical or business information to prevent the serious harm to Moderna which would be caused by its public release as outlined in Dr. Parsons's Declaration.

IV. CONCLUSION

For the foregoing reasons, Moderna respectfully requests the Court grant Moderna's Motion to Seal with respect to Moderna's highly confidential information.

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May 9, 2024

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 9, 2024, upon the following in the manner indicated:

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